

### ***T-Cell Project:***

PROSPECTIVE COLLECTION OF DATA IN PATIENTS WITH PERIPHERAL T-CELL LYMPHOMA (Peripheral T-cell lymphoma unspecified; Angioimmunoblastic T-cell lymphoma; Extranodal NK/T-cell lymphoma; Enteropathy- type T-cell lymphoma; Hepatosplenic gamma-delta T-cell lymphoma; Subcutaneous panniculitis-like T-cell lymphoma; Anaplastic large-cell lymphoma, T/null cell, primary systemic type).

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### **Objectives**

The designed study follows up the previous one by the International T-cell Non-Hodgkin's Lymphoma Study Group and its purpose is to verify whether a prognostic collection of data would allow to achieve more accurate information to better define prognosis and to investigate on most adequate treatment strategies for these neoplasms.

### **Primary Endpoint**

5-year overall survival

### **Secondary Endpoint**

5-year event free survival

### **Additional Endpoints**

Remission rate with initial therapy  
5-year progression free survival

### **Inclusion Criteria**

1. Previously-untreated patients with *de novo* diagnosis of peripheral T-cell or NK/T-cell lymphoma:
  - Peripheral T-cell lymphoma unspecified;
  - Peripheral T-cell lymphoma, lymphoepitelioid variant;
  - Peripheral T-cell lymphoma, T-zone variant ;
  - Peripheral T-cell lymphoma, parafollicular variant ;
  - Angioimmunoblastic T-cell lymphoma;
  - Nasal NK/T-cell lymphoma;

- NK/T-cell lymphoma, nasal type;
  - Anaplastic large-cell lymphoma, T/null cell, ALK+, primary systemic type
  - Anaplastic large-cell lymphoma, T/null cell, ALK-, primary systemic type
  - Anaplastic large cell lymphoma, small cell variant, ALK+
  - Anaplastic large cell lymphoma, lymphohistiocytic variant, ALK+
  - Enteropathy- type T-cell lymphoma;
  - Hepatosplenic T-cell lymphoma;
  - Peripheral gamma-delta T-cell lymphoma;
  - Subcutaneous panniculitis-like T-cell lymphoma;
  - Unclassifiable peripheral T-cell Lymphoma
  - Unclassifiable NK-cell lymphoma
2. Age over 18
  3. Consecutive cases diagnosed at each participant Institution
  4. Tissue biopsies adequate for diagnosis and classification and available for centralized review
  5. Clinical data including baseline information on disease localization and laboratory parameters at staging, features of treatment adopted and assurance of follow-up updating for at least 5 years are requested
  6. Written informed consent

#### **Exclusion Criteria**

1. Age < 18
2. Diagnosis of T-cell or NK-cell leukemia or proliferation and other than mature types including:
  - Adult T-cell leukemia/lymphoma;
  - Blastic NK-cell leucemia/lymphoma;
  - Aggressive NK-cell leucemia
  - T-cell large granular lymphocytic leukemia
  - T-cell large granular lymphocytic proliferation
  - NK-cell large granular lymphocytic proliferation
  - T-cell prolymphocytic leukemia
  - Precursor T-cell lymphoblastic leukemia/lymphoma
  - Mycosis fungoides;
  - Sézary syndrome;
  - Primary cutaneous ALCL.

**Planned Sample Size:** 460 patients with PTCL-U and 460 patients with AILD. Since the definition of a sample size for more uncommon PTCLs subtypes is not possible due to their rarity, the study is designed only to prospective collecting all cases of rarer histologies in the same time frame PTCL-U and AILD are planned to be accrued.

**Estimated Study Duration:** 2 years for accrual and a minimum follow-up of 5 years.

**Data collection:** Data collection will be performed on-line on a key restricted accessible web-database.

#### **Study Design**

The present study is designed as a prospective collection of information potentially useful to predict the prognosis of newly diagnosed patients with the more frequent subtypes of Peripheral T-cell lymphoma (*Peripheral T-cell lymphoma unspecified* and *Angioimmunoblastic T-cell lymphoma*) and to better define clinical characteristics and outcome of the more uncommon subtypes (*Extranodal NK/T-cell lymphoma; Enteropathy- type T-cell lymphoma; Hepatosplenic gamma-delta T-cell lymphoma; Subcutaneous panniculitis-like T-cell lymphoma; Anaplastic large-cell lymphoma, T/null cell, primary systemic type*).

Study Flow Chart

